WE CLAIM:

1. A method of estimating a withdrawal interval for an adjusted dose of a compound from a prior withdrawal time for a corresponding prior dose of said compound, corresponding prior half-life data and a tolerance concentration, for a tissue of interest, said method comprising the following steps that are performed in a data processing system:

accepting selection of an adjusted dose for said compound for which a withdrawal interval is to be determined;

extrapolating a withdrawal interval from *(a)* said prior dose, *(b)* said prior withdrawal time, *(c)* said half-life data, and *(d)* said tolerance concentration.

2. A method according to claim 1, wherein said prior dose and said adjusted dose are carried out under different conditions, and said extrapolating step is preceded by the step of:

normalizing the conditions of said prior dose to the conditions of said adjusted dose.

3. A method according to claim 1, wherein said extrapolating step is carried out based on the slope of the line representing the tissue depletion for said compound in said tissue at said prior dose corresponding to the slope of the line representing the virtual depletion of the 99^{th} percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

4. A method according to claim 1, wherein said extrapolating step is carried out based on the depletion rate constant for said compound in said tissue at said prior dose corresponding to the virtual depletion rate constant representing the virtual depletion of the 99^{th} percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

5. A method according to claim 1, wherein said half-life data is an empirically determined effective residue half-life.

6. A method according to claim 5, wherein said step of extrapolating a withdrawal interval is carried out by:

determining a half-life multiplier from said first withdrawal time and said residue half-life;

determining a concentration at time zero for said first dose from said tolerance concentration and said half-life multiplier;

determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and then

calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

7. A method according to claim 6, wherein said calculating step comprises executing the formula:

WDI=ERH x Ln(C**/TOL) x 1.44

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

8. A method according to claim 1, wherein said half-life data is a half-life multiplier.

9. A method according to claim 8, wherein said step of extrapolating a withdrawal interval is carried out by:

determining a residue half life from said first withdrawal time and said predetermined half -life multiplier;

determining a concentration at time zero for said first dose from said tolerance concentration and said predetermined half-life multiplier;

determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and then

calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

10. A method according to claim 9, wherein said calculating step comprises executing the formula:

WDI=ERH x Ln(C**/TOL) x 1.44

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

11. A method according to claim 10, wherein said half-life multiplier is 5.

12. A method according to claim 1, wherein said tolerance concentration is an approved tolerance.

13. A method according to claim 1, wherein said tolerance concentration is a provisional acceptable residue determined by the method comprising:

providing an acceptable daily intake for said compound;

partitioning said acceptable daily intake among tissues according to a set of partitioning instructions; and

deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake.

14. A method according to claim 1, wherein said compound is monitored in said tissue by monitoring a marker residue, and wherein tolerance concentration is a provisional acceptable tolerance determined by the method comprising:

providing an acceptable daily intake for said compound;

partitioning said acceptable daily intake among tissues according to a set of partitioning instructions;

deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake; and

determining a provisional acceptable tolerance from said provisional acceptable residue.

15. A method according to claim 1, wherein said adjusted dose is modified from said prior dose for species differences, disease differences or both.

16. A method according to claim 15, wherein said adjusted dose is modified for disease differences selected from the group consisting of a change in clearance, a change in volume of distribution, and combinations thereof.

17. A method according to claim 15, wherein said adjusted dose is modified for species differences with allometric data.

18. A method according to claim 1, further comprising the step of:

confirming said withdrawal interval with field or regulatory data.

19. A data processing system for estimating a withdrawal interval for an adjusted dose of a compound from a prior withdrawal time for a corresponding prior dose of said compound, corresponding half –life data and a tolerance concentration, for a tissue of interest, said data processing system comprising:

means for accepting selection of an adjusted dose for said compound for which a withdrawal interval is to be determined;

means for extrapolating a withdrawal interval from *(a)* said prior dose, *(b)* said prior withdrawal time, *(c)* said half-life data, and *(d)* said tolerance concentration.

20. A system according to claim 19, wherein said prior dose and said adjusted dose are carried out under different conditions, said system further comprising:

means for normalizing the conditions of said prior dose to the conditions of said adjusted dose.

21. A system according to claim 19, wherein said means for extrapolating is based on the slope of the line representing the tissue depletion for said compound in said tissue at said prior dose corresponding to the slope of the line representing the virtual depletion of the 99th percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

22. A system according to claim 19, wherein said means for extrapolating is based on the depletion rate constant for said compound in said tissue at said prior dose corresponding to the virtual depletion rate constant representing the virtual depletion of the 99th percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

23. A system according to claim 19, wherein said half-life data is an empirically determined effective residue half-life, and wherein said means for extrapolating includes:

means for determining a half-life multiplier from said first withdrawal time and said residue half-life;

means for determining a concentration at time zero for said first dose from said tolerance concentration and said half-life multiplier;

means for determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and

means for calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

24. A system according to claim 23, wherein said means for calculating executes the formula:

$$WDI=ERH \times Ln(C^{**}/TOL) \times 1.44$$

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

25. A system according to claim 19, wherein said half-life data is a half-life multiplier, and wherein said means for extrapolating includes:

means for determining a residue half life from said first withdrawal time and said predetermined half -life multiplier;

means for determining a concentration at time zero for said first dose from said tolerance concentration and said predetermined half-life multiplier;

means for determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and

means for calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

26. A system according to claim 25, wherein said means for calculating executes the formula:

WDI=ERH x Ln(C**/TOL) x 1.44

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

27. A system according to claim 26, wherein said half-life multiplier is 5.

28. A system according to claim 19, wherein said tolerance concentration is an approved tolerance.

29. A system according to claim 19, wherein said tolerance concentration is a provisional acceptable residue and said system further comprises:

means for accepting selection of an acceptable daily intake for said compound;

means for partitioning said acceptable daily intake among tissues according to a set of partitioning instructions; and

means for deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake.

30. A system according to claim 19, wherein said compound is monitored in said tissue by monitoring a marker residue, wherein tolerance concentration is a provisional acceptable tolerance, and said system further comprises:

means for accepting selection of an acceptable daily intake for said compound;

means for partitioning said acceptable daily intake among tissues according to a set of partitioning instructions;

means for deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake; and

means for determining a provisional acceptable tolerance from said provisional acceptable residue.

31. A system according to claim 19, further comprising means for modifying said adjusted dose from said prior dose for species differences, disease differences or both.

32. A system according to claim 31, wherein said adjusted dose is modified for disease differences selected from the group consisting of a change in clearance, a change in volume of distribution, and combinations thereof.

33. A system according to claim 31, wherein said adjusted dose is modified for species differences with allometric data.

34. A system according to claim 19, further comprising:

means for confirming said withdrawal interval with field or regulatory data.

35. A computer program product for estimating a withdrawal interval for an adjusted dose of a compound from a prior withdrawal time for a corresponding prior dose of said compound, corresponding half-life data and a tolerance concentration, for a tissue of interest, said computer program product comprising a computer-readable storage medium having computer-readable program code means embodied in the medium, the computer-readable program code means comprising:

computer-readable program code means for accepting selection of a prior dose of said compound;

computer-readable program code means for accepting selection of an adjusted dose for said compound for which a withdrawal interval is to be determined;

computer-readable program code means for extrapolating a withdrawal interval from *(a)* said prior dose, *(b)* said prior withdrawal time, *(c)* said half-life data, and *(d)* said tolerance concentration.

36. A product according to claim 35, wherein said prior dose and said adjusted dose are carried out under different conditions, said system further comprising:

computer-readable program code means for normalizing the conditions of said prior dose to the conditions of said adjusted dose.

37. A product according to claim 35, wherein said computer-readable program code means for extrapolating is based on the slope of the line representing the tissue depletion for said compound in said tissue at said prior dose corresponding to the slope of the line representing the virtual depletion of the 99th percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

38. A product according to claim 35, wherein said computer-readable program code means for extrapolating is based on the depletion rate constant for said compound in said tissue at said prior dose corresponding to the virtual depletion rate constant representing the virtual depletion of the 99th percentile of the population of depleting animals for said compound in said tissue at said adjusted dose.

39. A product according to claim 35, wherein said half-life data is an empirically determined effective residue half-life, and wherein said computer-readable program code means for extrapolating includes:

computer-readable program code means for determining a half-life multiplier from said first withdrawal time and said residue half-life;

computer-readable program code means for determining a concentration at time zero for said first dose from said tolerance concentration and said half-life multiplier;

computer-readable program code means for determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and

computer-readable program code means for calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

40. A product according to claim 39, wherein said computer-readable program code means for calculating executes the formula:

WDI=ERH x Ln(C**/TOL) x 1.44

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

41. A product according to claim 35, wherein said half-life data is a half-life multiplier, and wherein said computer-readable program code means for extrapolating includes:

computer-readable program code means for determining a residue half life from said first withdrawal time and said predetermined half-life multiplier;

computer-readable program code means for determining a concentration at time zero for said first dose from said tolerance concentration and said predetermined half-life multiplier;

computer-readable program code means for determining a concentration at time zero for said second dose from said first dose, said second dose, and said concentration at time zero for said first dose; and

computer-readable program code means for calculating said withdrawal interval from *(a)* said residue half-life, *(b)* said concentration at time zero for said second dose, and *(c)* said tolerance concentration.

42. A product according to claim 41, wherein said computer-readable program code means for calculating executes the formula:

WDI=ERH x Ln(C**/TOL) x 1.44

wherein:

WDI=withdrawal interval;

ERH=effective residue half-life;

C**=concentration at time zero for said second dose; and

TOL=tolerance concentration.

43. A product according to claim 42, wherein said half-life multiplier is 5.

44. A product according to claim 35, wherein said tolerance concentration is an approved tolerance.

45. A product according to claim 35, wherein said tolerance concentration is a provisional acceptable residue and said system further comprises:

computer-readable program code means for accepting selection of an acceptable daily intake for said compound;

computer-readable program code means for partitioning said acceptable daily intake among tissues according to a set of partitioning instructions; and

computer-readable program code means for deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake.

46. A product according to claim 35, wherein said compound is monitored in said tissue by monitoring a marker residue, wherein tolerance concentration is a provisional acceptable tolerance, and said system further comprises:

computer-readable program code means for accepting selection of an acceptable daily intake for said compound;

computer-readable program code means for partitioning said acceptable daily intake among tissues according to a set of partitioning instructions;

computer-readable program code means for deriving said provisional acceptable residue for said tissue of interest from said partitioned acceptable daily intake; and

computer-readable program code means for determining a provisional acceptable tolerance from said provisional acceptable residue.

47. A product according to claim 35, further comprising computer-readable program code means for modifying said adjusted dose from said prior dose for species differences, disease differences or both.

48. A product according to claim 47, wherein said adjusted dose is modified for disease differences selected from the group consisting of a change in clearance, a change in volume of distribution, and combinations thereof.

49. A product according to claim 47, wherein said adjusted dose is modified for species differences with allometric data.

50. A product according to claim 35, further comprising computer-readable code means for confirming said withdrawal interval with field or regulatory data.

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